IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Julie Straub, David Altreuter, Howard Bernstein, Donald E. Chickering, III, Sarwat Khattak, and Greg Randall		
Serial No.:	10/053,929	Art Unit:	1618
Filed:	January 22, 2002	Examiner:	Blessing M. Fubara
For:	*POROUS DRUG MATRICES AND METHODS OF MANUFACTURE THEREOF*		

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from the final rejection of claims 16-21 and 34 in the Office Action mailed December 8, 2006 in the above-identified patent application. A Notice of Appeal was filed on April 9, 2007. A response after final was filed on June 25, 2007 with a Petition for Extension of Time for one-month, along with the required fee. The Commissioner is hereby authorized to charge $500.00, the fee for the filing of this Appeal Brief for a large entity, to Deposit Account No. 50-3129.

It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

(1) REAL PARTY IN INTEREST

The real party in interest of this application is Acusphere, Inc., the assignee.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(3) STATUS OF CLAIMS

Claims 16-21 and 34 are pending. Claims 1-15 and 22-33 have been cancelled. Claims 16-21 and 34 are on appeal. The text of each claim on appeal, as pending, is set forth in an Appendix to this Appeal Brief.

(4) STATUS OF AMENDMENTS

Responses after final rejection were filed on March 6, 2007 and June 25, 2007. The claims were not amended after final rejection. The claims were last amended in an Amendment filed September 18, 2006. An appendix sets forth the claims on appeal.

(5) SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 16 defines a method for making a pharmaceutical composition comprising a porous matrix formed of at least one hydrophilic or hydrophobic excipient and microparticles of a drug, wherein the microparticles have a mean diameter between about 0.1 and 5 μm and a total surface area greater than about 0.5 m^2/mL, and wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0 g/mL and having a total surface area of greater than or equal to 0.2 m^2/g. Claim 16 requires the following steps: (a) dissolving a drug in a volatile solvent to form a drug solution, (b) combining at least one volatile

solid pore forming agent with the drug solution to form an emulsion, suspension, or second solution, (c) incorporating at least one excipient into the emulsion, suspension, or second solution, wherein the excipient is selected from the group consisting of hydrophobic and hydrophilic excipients which enhance dissolution rate, which stabilize drug in amorphous form by preventing crystallization, and which stabilize drug in crystalline form by inhibiting crystal growth, and (d) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug and excipient (page 3, lines 14-25; and page 4, lines 2-5).

Dependent claim 17 specifies that the volatile solvent can be removed using a technique chosen from spray drying, evaporation, fluid bed drying, lyophilization, vacuum drying, or a combination thereof (page 22, lines 5-8).

Dependent claim 18 specifies that the excipients may be polymers, amino acids, wetting agents, sugars, preservatives, pegylated excipients, tonicity agents, or combinations thereof (page 13, line 8 to page 19, line 18).

Dependent claim 20 specifies that the pore forming agent may be a volatile salt (page 19, lines 21-22). Dependent claim 21 further specifies that the volatile salt may be ammonium bicarbonate, ammonium acetate, ammonium chloride, ammonium benzoate, and mixtures thereof (page 20, lines 28-30).

Dependent claim 19 specifies that the matrix contains between 1 and 95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient which enhances the rate of drug dissolution, stabilizes the drug in crystalline form by inhibiting crystal growth or stabilizes

the drug in amorphous form by preventing crystallization (page 6, lines 2-6 and page 4, lines 5-9).

Dependent claim 34 specifies that the drug may be an analgesic or antipyretic, antiasthmatic, anti-inflammatory, antimigraine agent, antiarthritic agent, anticonvulsant, antibacterial agent, antiviral agent, or antimicrobial (page 7, line 5 to page 11, line 27).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole issue presented on appeal is:

(1) whether claims 16-21 and 34 are non-obvious as required by 35 U.S.C. § 103(a) over U.S. Patent Application Publication No. 2001/0018072 to Unger ("Unger").

(7) ARGUMENT

(i) Rejections Under 35 U.S.C. § 103

Legal Standard

Obviousness is a legal conclusion based on underlying facts of four general types, all of which must be considered by the examiner: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459 (1966). The *Graham* analysis was recently affirmed by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007).

The Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a). This analysis is

commonly referred to as the "TSM test". Indeed, the examiner's attention is drawn to the following quote by the Court in *KSR*:

> The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. [. . .] There is no necessary inconsistency between the [TSM] test and the *Graham* analysis.

KSR, 127 S. Ct. at 1727.

The obviousness analysis requires looking at the invention as a whole. "Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness." *Gillette Co. v. S.C. Johnson & Sons, Inc.*, 919 F.2d 720, 724, 16 U.S.P.Q.2d 1923 (Fed. Cir. 1990); *see Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986).

Hindsight analysis, such as picking and choosing from prior art references using the claimed invention as a template, has long been forbidden. *See e.g. In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988), stating "One cannot use hindsight reconstruction to pick and choose among isolated disclosures on the prior art to deprecate the claimed invention." In *KSR*, the

Court also warned against the use of hindsight analysis in making an obviousness determination. The Court stated, "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." (*KSR*, 127 S. Ct. at 1742, citing *Graham*, 383 U.S. at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'" (quoting M*onroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412, 141 U.S.P.Q. 549 (6th Cir. 1964))).

In response to the *KSR* decision, the Deputy Commissioner for the USPTO issued a memorandum stating: "[I]n formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed." Memorandum from Margaret A. Forcarino to Technology Center Directors (May 3, 2007).

Analysis

As discussed above, the Court recently reaffirmed the *Graham* factors, which are analyzed below:

(a) Determining the scope and contents of the prior art

The scope and contents of the prior art must be made *at the time the invention was made*. The requirement "at the time the invention was made" is to avoid impermissible hindsight. "It is difficult but necessary that the decision maker forget what he or she has been taught [...] about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the

references, and who is normally guided by the then-accepted wisdom in the art." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983).

Unger describes a solid porous matrix containing a surfactant in combination with a bioactive agent (page 1, paragraph 0013). The matrix may be prepared by (1) combining a surfactant and a therapeutic, together with a solvent, to form an emulsion containing random aggregates of the surfactant and the therapeutic, and (2) processing the emulsion by controlled drying, or controlled agitation and controlled drying to form the solid porous matrix (abstract and page 1, paragraph 0014).

Unger is concerned with the targeted delivery of therapeutics to a particular region of patient (page 1, paragraph 0002). The compositions described in Unger may contain a stabilizing material, which is capable of improving the stability of the vesicles (e.g., liposomes, lipospheres, particles, etc.) containing gases, gaseous precursors, steroid prodrugs, targeting ligands, and/or other bioactive agents (page 2, paragraph 0031). The stabilizing material can be used to prevent the escape of gases, gaseous precursors, steroid prodrugs, targeting ligands, and/or other bioactive agents.

(b) Ascertaining the differences between the prior art and the claims

In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 U.S.P.Q. 698 (Fed. Cir. 1983).

The Claimed method

The claims define a method for making porous drug matrices. As discussed in the specification, such drug matrices are particularly useful for increasing the dissolution rates for drugs, especially drugs with low aqueous solubility (*see* page 2, lines 23-27). The matrices contain at least one excipient which enhances the dissolution rate of the drug, stabilizes the drug in an amorphous form by preventing crystallization, or stabilizes the drug in crystalline form by inhibiting crystal growth.

Independent claim 16 and its dependent claims, claims 17-21 and 34, define methods for making a pharmaceutical composition that contains a porous matrix formed of at least one hydrophilic or hydrophobic excipient and microparticles of a drug. As specified in claim 16, the method requires the following steps:

(a) dissolving a drug in a volatile solvent to form a drug solution,

(b) combining at least one volatile solid pore forming agent with the drug solution to form an emulsion, suspension, or second solution,

(c) incorporating at least one excipient into the emulsion, suspension, or second solution, wherein the excipient is selected from the group consisting of hydrophobic and hydrophilic excipients which enhance dissolution rate, which stabilize drug in amorphous form by preventing crystallization, and which stabilize drug in crystalline form by inhibiting crystal growth, and

(d) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug and excipient.

Independent claim 16 also specifies physical properties of the composition produced by this method. The resulting composition contains microparticles of drug that have a mean diameter between about 0.1 and 5 μm and a total surface area greater than about 0.5 m^2/mL. Additionally the composition contains a dry porous matrix in a dry powder form, which has a TAP density of less than or equal to 1.0 g/mL and a total surface area of greater than or equal to 0.2 m^2/g.

As discussed in detail below, Unger describes a different method and different compositions are produced using Unger's method.

Unger does not disclose or suggest elements (b), (c), and (d) of claim 16

Unger does not disclose or suggest adding a volatile solid pore forming agent to the drug solution and then removing the volatile solid pore forming agent

Unger describes the use of gases or gaseous precursors, which are entrapped within the matrix (page 20, paragraph 0160 to page 22, paragraph 0175). Unger alleges that the entrapped gas provides the solid porous matrix with enhanced reflectivity. The gas and/or gaseous precursors are not "pore forming agents" nor are they removed from the matrix. Unger also describes the use of gaseous precursors as a solvent in the preparation of the solid matrix (page 20, paragraph 0161). Solvents, by definition, are generally liquids. In contrast, the claimed method requires the addition of a volatile solid pore forming agent, which is removed and upon removal, forms a porous matrix.

While Unger discloses that the gaseous precursor may be added to the surfactant and the therapeutic and removed during processing (page 20, paragraph 0161), this disclosure is

specifically in regard to gaseous precursors that are used as a solvent in the preparation of a solid porous matrix. None of Unger's examples describe adding a volatile solid pore forming agent to a drug solution to form a suspension, emulsion, or second solution and then removing the volatile solid pore forming agent to form a porous matrix.

In the Advisory Action mailed April 26, 2007, the Examiner stated "...Unger teaches the steps of dissolving the drug in a volatile organic solvent in the presence of pore forming agents, such as bicarbonate of PEG, lyophilizes or vacuum dries or spray dries the suspension or emulsion to form the porous matrix is described in paragraphs 0184-0190". This statement mischaracterizes Unger's disclosure.

First, there is no reference to bicarbonate of PEG in Unger.

Second, paragraphs 0184-190 cited by the Examiner do not disclose or suggest the use a volatile solid pore forming agent to form a porous matrix. Paragraph 0184 discloses that a solid porous matrix containing a surfactant and a therapeutic is prepared by combining a solvent, a surfactant, and a therapeutic to form an emulsion in the form of a random aggregate. In the case of spray drying, the emulsion or colloidal suspension is placed into association with a blowing agent, such as methylene chloride. Methylene chloride is a volatile organic solvent; it is not a volatile solid pore forming agent as required by the claims.

Unger's Example 1 does not meet the limitations of Claim 16

In the Final Office Action mailed December 8, 2006, the Examiner alleges that prophetic Example 1 in Unger describes steps (a), (b), and (d) of claim 16. This allegation is incorrect. Example 1 describes the encapsulation of dexamethasone in PEG Telomer B, which is a

surfactant. Unger predicts that 20% of the PEG-Telomer B aggregate complex is dexamethasone. PEG Telomer B is not a volatile pore forming agent. PEG Telomer B is not removed from the mixture. Further, even if one could argue that PEG Telomer B is a volatile pore forming agent, it is not a volatile solid pore forming agent. PEG Telomer B is a liquid having a boiling point of 200°C (*see* the enclosed Material Safety Data Sheet for PEG Telomer B, originally submitted with Response filed June 25, 2007). Example 1 does not disclose the addition of a volatile solid pore forming agent to a drug solution. Further, Example 1 does not disclose removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug and excipient as required by claim 16.

Volatile Solid Pore Forming Agents are a subset of Pore Forming Agents

Claim 16 requires a volatile solid pore forming agent. "Volatile" agents are agents that change readily from a solid or liquid to a vapor (*see* the enclosed definition from www.wordnet.princeton.edu, originally submitted with Response filed March 6, 2007). The compounds are typically evaporated using added heat and/or vacuum (page 20, lines 22-24 of the specification).

The references cited by the Examiner in the Final Office Action mailed December 8, 2006 disclose agents that form pores by dissipating out of the composition *in situ* into the surrounding tissues or bodily fluids; they are not volatilized during formation of the porous matrix as required by the claims. Sodium chloride has a melting point of 800°C and a boiling point of 1,465°C (*see* the enclosed Material Safety Data Sheet for salt, originally submitted with Response filed March 6, 2007). Starch decomposes at 250°C, which is before its melting point

(*see* the Material Safety Data Sheet for starch, originally submitted with Response filed March 6, 2007). Thus, these materials do not evaporate readily at relatively low temperatures and pressures; i.e., they are not volatile.

Further, the pore forming agents required by the pending claims are removed during processing, i.e. prior to introducing the composition into the body; not *in situ* as required by the references cited by the Examiner. Contrary to the Examiner's assertion, any agent that is listed in any prior art reference as a "pore forming agent" does not necessarily meet the limitations of claim 16.

Unger does not disclose compositions containing an excipient which enhances the dissolution rate of the drug, stabilizes the drug in an amorphous form by preventing crystallization, or stabilizes the drug in crystalline form by inhibiting crystal growth

As discussed above, Unger discloses the use of a stabilizing material. However, Unger's stabilizing material is used to stabilize the vesicle containing the active agent and/or to prevent escape of the gases, gaseous precursors, or bioactive agents. Unger does not disclose or suggest the use of at least one excipient which enhances the dissolution rate of the drug, stabilizes the drug in an amorphous form by preventing crystallization, or stabilizes the drug in crystalline form by inhibiting crystal growth.

Unger does not disclose or suggest microparticles with the properties required by claim 16

Claim 16 specifies the properties of the compositions formed using the claimed method. Unger does not disclose or suggest that the microparticles formed using its process have the properties specified by claim 16.

(c) Resolving the level of ordinary skill in the art

One of ordinary skill in the art at the time of the earliest priority date would likely have a master's degree in chemistry, chemical engineering, or pharmaceutics with at least approximately five years experience, or a Ph.D. in chemistry, chemical engineering, or pharmaceutics with at least approximately three years experience.

(d) Evaluating evidence of secondary considerations

Secondary considerations to be considered include commercial success, long felt but unresolved needs, failure of others, etc.

The claims are drawn to methods of making pharmaceutical compositions. These methods are particularly useful for formulating pharmaceutical compositions containing drugs having low solubility. As discussed in the specification, the bioavailability of a drug can be limited by poor dissolution of the drug into aqueous bodily fluids following administration (page 1, lines 17-18). This rate- limiting step can be critical to rapidly attaining therapeutically effective drug levels (page 1, lines 18-20).

Traditional approaches to parenteral delivery of poorly soluble drugs include using large volumes of aqueous diluents, solubilizing agents, detergents, non-aqueous solvents, or non-

physiological pH solutions (page 1, lines 20-23). These formulations, however, can increase the systemic toxicity of the drug composition or damage tissues the site of administration (page 1, lines 23-25).

Other approaches disclosed in the prior art have focused on the physical form of the drug itself. For example, drugs have been prepared in nanoparticulate form. Nanoparticles, however, can be difficult to produce and maintain in a stable form due to their tendency to flocculate or agglomerate, particularly in the absence of surface modifying agents absorbed or coated onto the particles (page 1, line 31 to page 2, line 3). Further, techniques used for nanonization are typically undesirable due to: (1) the time it takes to process a single batch (e.g., several days); (2) scale up of such techniques can be difficult and costly; and (3) the process can be difficult to conduct aseptically (page 2, lines 3-8). Thus, at the time of the priority application, there existed an unmet need for formulations containing poorly soluble drugs which exhibit increased dissolution of the drug.

Additionally, the claimed methods are quite versatile and are generally useful for increasing the dissolution rates of drugs.

Application of the *Graham* factors demonstrates that one or ordinary skill in the art would not have been motivated to modify Unger to arrive at the claimed methods. Unger is concerned with targeted drug delivery, not formulating poorly soluble drugs to have enhanced dissolution *in vivo*. Unger describes the use of stabilizing materials to stabilize the vesicle containing the active agent, not to enhance dissolution or prevent crystallization of the drug as required by claim 16. Unger does not disclose or suggest steps (b), (c), and (d) of claim 16.

Unger does not disclose or suggest microparticles having the properties defined in claim 16. One of ordinary skill in the art would not be motivated to modify Unger to arrive at the claimed methods. Therefore claims 16-21 and 34 are not obvious in view of Unger.

Claim 18 is not obvious in view of Unger

In addition to the arguments provided above with respect to claim 16 and its dependent claims, claim 18 is non obvious because Unger does not disclose or suggest the excipients listed in claim 18 to enhance the dissolution rate of the drug, stabilize the drug in an amorphous form by preventing crystallization, or stabilize the drug in crystalline form by inhibiting crystal growth. Accordingly, claim 18 is not obvious over Unger.

Claims 19 and 20 are not obvious in view of Unger

In addition to the arguments provided above with respect to claim 16 and its dependent claims, claims 19 and 20 are non obvious because Unger does not disclose or suggest the use of volatile salts as pore forming agents. Unger does not disclose or suggest the use of volatile salts as solid pore forming agents, let alone the specific salts listed in claim 20. Accordingly, claims 19 and 20 are not obvious over Unger.

(8) SUMMARY AND CONCLUSION

Unger does not disclose or suggest a method for making microparticles comprising forming a drug solution, adding a volatile solid pore forming agent to the drug solution to form a suspension, emulsion, or second solution, and removing the pore forming agent to form a porous matrix as required by claim 16. Unger does not disclose or suggest that the microparticles formed using its process have the properties required by claim 16. Unger does not disclose or

suggest every element of the claims. Further, the Examiner has provided no reason why one of ordinary skill in the art would be motivated to modify Unger to arrive at the claimed methods. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness.

For the foregoing reasons, Appellant submits that claims 16-21 and 34 are patentable.

Respectfully submitted,

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Date: July 9, 2007

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Claims Appendix: Claims On Appeal

16. A method for making a pharmaceutical composition comprising a porous matrix formed of at least one hydrophilic or hydrophobic excipient and microparticles of a drug, wherein the microparticles have a mean diameter between about 0.1 and 5 μm and a total surface area greater than about 0.5 m^2/mL, and wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0 g/mL and having a total surface area of greater than or equal to 0.2 m^2/g, comprising

(a) dissolving a drug in a volatile solvent to form a drug solution,

(b) combining at least one volatile solid pore forming agent with the drug solution to form an emulsion, suspension, or second solution,

(c) incorporating at least one excipient into the emulsion, suspension, or second solution, wherein the excipient is selected from the group consisting of hydrophobic and hydrophilic excipients which enhance dissolution rate, which stabilize drug in amorphous form by preventing crystallization, and which stabilize drug in crystalline form by inhibiting crystal growth, and

(d) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug and excipient.

17. The method of claim 16 wherein step (d) is conducted using a process selected from spray drying, evaporation, fluid bed drying, lyophilization, vacuum drying, or a combination thereof.

18. The method of claim 16 wherein the excipients are selected from the group consisting of polymers, amino acids, wetting agents, sugars, preservatives, pegylated excipients, tonicity agents, and combinations thereof.

19. The method of claim 16 wherein the matrix comprises between 1 and 95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient which enhances the rate of drug dissolution, stabilizes the drug in crystalline form by inhibiting crystal growth or stabilizes the drug in amorphous form by preventing crystallization.

20. The method of claim 16 wherein the pore forming agent is a volatile salt.

21. The method of claim 20 wherein the volatile salt is selected from the group consisting of ammonium bicarbonate, ammonium acetate, ammonium chloride, ammonium benzoate, and mixtures thereof.

34. The method of claim 16, wherein the drug is selected from the group consisting of analgesics or antipyretics, antiasthmatics, anti-inflammatories, antimigraine agents, antiarthritic agents, anticonvulsants, antibacterial agents, antiviral agents, and antimicrobials.

Evidence Appendix

1. Material Safety Data Sheet for PEG Telomer B
2. Definition of the term "volatile"
3. Material Safety Data Sheet for Sodium Chloride (salt)
4. Material Safety Data Sheet for Starch

Related Proceedings Appendix

None

SIGMA-ALDRICH

Material Safety Data Sheet

Date Printed: 21/APR/2005
Date Updated: 16/MAR/2004
Version 1.1
According to 91/155/EEC

Classified as Hazardous according to the criteria of EU Annex 1 and NOHSC.

1 - Product and Company Information

Product Name	ZONYL FSO-100 FLUOROSURFACTANT
Product Number	421456
Company	Sigma-Aldrich Pty, Ltd Unit 2, 14 Anella Avenue Castle Hill NSW 1765 Australia
Technical Phone #	+61 2 9841 0555
Fax	+61 2 9841 0500
Emergency Phone #	+61 2 9841 0566

2 - Composition/Information on Ingredients

Product Name	CAS #	EC no	Annex I Index Number
PEG TELOMER B	None	None	None

3 - Hazards Identification

SPECIAL INDICATION OF HAZARDS TO HUMANS AND THE ENVIRONMENT
May cause cancer. May cause heritable genetic damage.

4 - First Aid Measures

AFTER INHALATION
If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

AFTER INGESTION
If swallowed, wash out mouth with water provided person is conscious. Call a physician.

5 - Fire Fighting Measures

EXTINGUISHING MEDIA
Suitable: Water spray. Carbon dioxide, dry chemical powder, or appropriate foam.

SPECIAL RISKS
Specific Hazard(s): Emits toxic fumes under fire conditions.

SPECIAL PROTECTIVE EQUIPMENT FOR FIREFIGHTERS
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6 - Accidental Release Measures

PERSONAL PRECAUTION PROCEDURES TO BE FOLLOWED IN CASE OF LEAK OR SPILL
Evacuate area.

PROCEDURE(S) OF PERSONAL PRECAUTION(S)
Wear self-contained breathing apparatus, rubber boots, and heavy rubber gloves. Wear disposable coveralls and discard them after use.

METHODS FOR CLEANING UP
Cover with dry lime or soda ash, pick up, keep in a closed container, and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete.

7 - Handling and Storage

HANDLING
Directions for Safe Handling: Do not breathe vapor. Avoid all contact. Do not get in eyes, on skin, on clothing. Avoid prolonged or repeated exposure.

STORAGE
Conditions of Storage: Keep tightly closed. Store in a cool dry place.

8 - Exposure Controls / Personal Protection

ENGINEERING CONTROLS
Use only in a chemical fume hood. Safety shower and eye bath.

GENERAL HYGIENE MEASURES
Wash thoroughly after handling. Discard contaminated clothing and shoes.

PERSONAL PROTECTIVE EQUIPMENT
Special Protective Measures: Wear appropriate government approved respirator, chemical-resistant gloves, safety goggles, other protective clothing.

9 - Physical and Chemical Properties

Appearance	N/A	
Property	**Value**	**At Temperature or Pressure**
pH	N/A	
BP/BP Range	200 °C	
MP/MP Range	N/A	
Flash Point	107 °C	Method: closed cup
Flammability	N/A	
Autoignition Temp	N/A	
Oxidizing Properties	N/A	
Explosive Properties	N/A	
Explosion Limits	N/A	
Vapor Pressure	N/A	
SG/Density	1.36 g/cm3	
Partition Coefficient	N/A	
Viscosity	N/A	
Vapor Density	N/A	
Saturated Vapor Conc.	N/A	
Evaporation Rate	N/A	
Bulk Density	N/A	
Decomposition Temp.	N/A	

Solvent Content	N/A
Water Content	N/A
Surface Tension	N/A
Conductivity	N/A
Miscellaneous Data	N/A
Solubility	N/A

10 - Stability and Reactivity

STABILITY
Stable: Stable.
Materials to Avoid: Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS
Hazardous Decomposition Products: Carbon monoxide, Carbon dioxide.

HAZARDOUS POLYMERIZATION
Hazardous Polymerization: Will not occur

11 - Toxicological Information

SIGNS AND SYMPTOMS OF EXPOSURE
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

ROUTE OF EXPOSURE
Multiple Routes: Harmful if swallowed, inhaled, or absorbed through skin. May cause irritation.

TARGET ORGAN INFORMATION
Liver. Kidneys. Nerves.

CHRONIC EXPOSURE - CARCINOGEN
Result: Carcinogen.

12 - Ecological Information

No data available.

13 - Disposal Considerations

SUBSTANCE DISPOSAL
Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.

14 - Transport Information

RID/ADR
Non-hazardous for road transport.

IMDG
Non-hazardous for sea transport.

IATA
Non-hazardous for air transport.

15 - Regulatory Information

CLASSIFICATION AND LABELING ACCORDING TO EU DIRECTIVES
INDICATION OF DANGER: T

Toxic.
R-PHRASES: 45 46
May cause cancer. May cause heritable genetic damage.
S-PHRASES: 53 23 36/37/39 45
Avoid exposure - obtain special instructions before use. Do not breathe vapor. Wear suitable protective clothing, gloves, and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16 - Other Information

DISCLAIMER
For R&D use only. Not for drug, household or other uses.

WordNet Search - 3.0 - WordNet home page - Glossary - Help

Word to search for: volatile Search WordNet

Display Options: (Select option to change) Change

Key: "S:" = Show Synset (semantic) relations, "W:" = Show Word (lexical) relations

Noun

- S: (n) **volatile** (a volatile substance; a substance that changes readily from solid or liquid to a vapor) *"it was heated to evaporate the volatiles"*

Adjective

- S: (adj) **volatile** (evaporating readily at normal temperatures and pressures) *"volatile oils"; "volatile solvents"*
- S: (adj) explosive, **volatile** (liable to lead to sudden change or violence) *"an explosive issue"; "a volatile situation with troops and rioters eager for a confrontation"*
- S: (adj) fickle, **volatile** (marked by erratic changeableness in affections or attachments) *"fickle friends"; "a flirt's volatile affections"*
- S: (adj) **volatile** (tending to vary often or widely) *"volatile stocks"; "volatile emotions"*

WordNet home page

Safety (MSDS) data for sodium chloride

Click here for data on sodium chloride in student-friendly format, from the HSci project

Glossary of terms on this data sheet.

The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers.

General

Synonyms: extra fine 200 salt, extra fine 325 salt, H.G. blending, salt, sea salt, table salt, common salt, dendritis, rock salt, top flake, white crystal, saline, halite, purex, USP sodium chloride
Molecular formula: NaCl
CAS No: 7647-14-5
EC No: 231-598-3

Physical data

Appearance: colourless crystals or white powder
Melting point: 804 C
Boiling point: 1413 C
Vapour density:
Vapour pressure: 1 mm Hg at 865C
Specific gravity: 2.16 g cm^{-3}
Flash point:
Explosion limits:
Autoignition temperature:
Solubility in water: 35.7 g/100g at 0C

Stability

Stable. Incompatible with strong oxidizing agents.

Toxicology

May cause eye irritation.

Toxicity data
(The meaning of any abbreviations which appear in this section is given here.)
ORL-RAT LD50 3000 mg kg^{-1}
ORL-MAN LDLO 1000 mg kg^{-1}
ORL-MUS LD50 4000 mg kg^{-1}
IPR-MUS LD50 2602 mg kg^{-1}
ICV-MUS LD50 131 mg kg^{-1}
SKN-RBT LD50 > 10000 mg kg^{-1}

Irritation data
(The meaning of any abbreviations which appear in this section is given here.)
SKN-RBT 50 mg/24h mld

Risk phrases
(The meaning of any risk phrases which appear in this section is given here.)
R36.

Personal protection

Not believed to present a significant hazard to health.

Safety phrases
(The meaning of any safety phrases which appear in this section is given here.)
S26 S36.

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Safety data for starch, soluble

Click here for data on starch in student-friendly format, from the HSci project

Glossary of terms on this data sheet.

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General

Synonyms: amylodextrin, soluble starch, amylopectin, amylum, argo brand corn starch, arrowroot starch, clearjel, farinex 100, genvis, keestar, maizena, maranta, melojel, meluna, penford gum 380, sorghum gum, corn starch, tapioca starch, tapon, trogum, numerous further trade and non-systematic names

Molecular formula: $(C_6H_{10}O_5)_n$

CAS No: 9005-84-9

EC No: 232-686-4

Physical data

Appearance: white powder

Melting point: typically decomposes around 250 C

Boiling point:

Vapour density:

Vapour pressure:

Density (g cm^{-3}):

Flash point:

Explosion limits:

Autoignition temperature:

Water solubility: slight in cold water, more substantial in hot water

Stability

Stable. Combustible. Incompatible with strong oxidizing agents.

Toxicology

Not hazardous according to Directive 67/548/EEC.

Toxicity data
(The meaning of any abbreviations which appear in this section is given here.)
IPR-MUS LD50 6600 mg kg^{-1}

Irritation data
(The meaning of any abbreviations which appear in this section is given here.)
SKN-HMN 300 ug/3d-I mld

Risk phrases
(The meaning of any risk phrases which appear in this section is given here.)

Transport information

Non-hazardous for air, sea and road freight.

Personal protection

Minimize exposure.

Safety phrases
(The meaning of any safety phrases which appear in this section is given here.)

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